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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,436	10/27/2003	Kathleen C.M. Campbell	SIU 7397	8942

321 7590 09/19/2007
SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

NOTIFICATION DATE	DELIVERY MODE
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09/19/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary

Application No.

10/694,436

Applicant(s)

CAMPBELL, KATHLEEN C.M.

Examiner

Shirley V. Gembeh

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 22-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-20 and 22-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/5/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/5/07 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/01/07 has been reviewed. The page number of item 1 of the non-patent literature has been added and is acknowledged.

Status of claims

Claims 1, 3-20 and 22-37 are pending.

Response to Arguments

The response filed 2/7/07 has been received and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in the prior Office action. Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Double Patenting

Applicant response to the double patenting over 6,187,817, 6,265,386, and 7,071,230 and a provisional double patenting over claims of 11/324,744 is considered and found persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15, 18-19, 26-28 and 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "from about" and "at least about" are not defined by the claim. The specification does not provide a standard for ascertaining the requisite degree. One of ordinary skill in the art would not be reasonably apprised of the scope of the invention because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or "about" (a broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about". Regarding "at least" (a lower limit) or "about" (a broadening limitation, both higher and lower), it is unclear what controls the metes and bounds of the phrase "at least about".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1614

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1 and 3-20 and 22-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuwelt, 2004/0198841 A1.

Neuwelt teaches ameliorating chemotherapeutic induced mucosal symptoms in patients undergoing radiation for oral, pharyngeal, and laryngeal cancer (see page 4, para 0051) by administering D-methionine (see page 3, para 0036), as in instant claims 1, 3-4. The reference teaches patients who undergo chemotherapy and radiation therapy to treat cancer suffer from mucosal injury, such as mucositis. As evident by the teaching (see page 1, para 0005), the reference teaches mucosal injury involves damage to the mucosal lining of the mouth, gastrointestinal tract, and any cavity lined by a mucous membrane. Thus the definition of mucositis, as in the instant claim 1, and administering an effective amount, are taught (see para 0033).

The D-, L- and D,L- forms are encompassed in Neuwelt's teaching as required by instant claims 4-6. Therefore, one of ordinary skill in the art would be motivated to use any of the forms and expect a successful result in doing so.

With regard to instant claims 7-9, the reference teaches thiol- based compounds may be orally administered prior to, concurrently, or after (see para 0069) and (0057). The teachings of the reference are drawn to radiation treatment based on the background teaching in the art.

The reference also teaches the protective agent, thiol-based compound, is administered at various time periods before chemotherapy or radiotherapy. The time

Art Unit: 1614

periods are 30 minutes, 1 and 6 hours are supported by the teachings (see 0069) as instant in claims 10-12.

The reference teaches dosage ranges as in instant claims 13-15 that would result in a blood serum level equivalent to that achieved by parenteral administration (see page 6, para 0068). Thus based on the calculation taught by the claims 18-19 are obvious. The calculation of the blood serum level of the compound can easily be determined as a percent, as required by instant claims 18-19.

One of ordinary skill in the art would have been motivated to use a methionine compound of the D-form to treat mucositis to patients undergoing chemotherapy because the reference makes obvious the claimed invention.

It is the Examiner's understanding that multiple administrations of the protective methionine agent as required by instant claim 16, constitutes a supplemental amount, as taught in paragraph 0069, last line, page 6.

With regard to instant claims 23-25, the reference teaches thiol-based compounds may be administered prior to, concurrently, or followed by administration of a chemotherapeutic agent (see 0069, page 6). Further, the reference teaches D-methionine may be administered orally (see 0057, page 5) as required by instant claim 26 and 30.

Examiner notes that the reference provides motivation to treat patients with mucositis by administering methionine to patients undergoing radiation. See paragraphs 0005; 0010; 0014; 0022 pages 1 and 2.

No claim is allowed.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
09//04/07

Phyllis Spivack
Phyllis Spivack
Primary Examiner

**PHYLLIS SPIVACK
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